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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,230	04/09/2004	Raphael J. Mannino	BSZ-050	1325

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LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,230	MANNINO ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.07

DETAILED ACTION

Claims 1-81, 102-110, 115-124, 142-152, 154-161, 164-166, 169-176 and 201-211 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-36, 79-81, 169-176, 102-105 and 203-211, drawn to a method of making a cargo moiety-cochleate comprising, introducing a cargo moiety to a liposome or negatively charged lipid in the presence of a solvent such that the cargo moiety associates with the liposome, classified in class 427, subclass 213.3.

II. Claim 37, 53-78, 115-124, 142-152 and 154, drawn to one or more cargo moiety-cochleates, classified in class 424, subclass 450.

III. Claims 38-43, 106-110, 155-161 and 164-166, drawn to a method of treating a subject, comprising administering one or more cargo moiety-cochleates, classified in class 514, subclass 44, for example.

IV. Claims 44-52, 201 and 202, drawn to a kit comprising a lipid or an aggregation inhibitor, classified in class 427, subclass 2.14.

Claim 42 is claimed in a Markush type format. However, the members of the group do not possess unity of invention and instead are patentably distinct from each other because each member is a different disease with distinct etiologies, concerns involving modeling of the disease, compounds that can be used to treat the disease, etc. Therefore, there is no functional

relationship between the members of the group (see MPEP § 803.02). Upon election of any group that contains any of the aforementioned claims, Applicant is required to elect a single disease, one of the members of the group, set forth in the claim. This is not an election of species, but rather an election of a distinct invention, owing to the functional differences between the members of the Markush-like group.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cargo moiety-cochleates of Group II can be made by a materially different process such as mixing a cargo moiety and a liposome and sonicating the mixture.

Inventions of Group II and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cargo moiety-cochleate can be used in a materially different process such as the delivery of a cargo moiety to cells cultured *in vitro*.

Inventions of Group IV and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit comprising a lipid or aggregation inhibitor can be used as a blocking agent in a materially different process such as a Western blotting.

Inventions of Group II and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The products of Group IV have a different chemical structure than the products of Group II. The function of the products of Group II and Group IV are different: delivering a cargo moiety to a cell (Group II) and making cargo moiety-cochleates (Group IV), for example.

Inventions of Group IV and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The product of Group IV is not made in or used by the method of Group III.

The inventions of Group I and Group III are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I and III comprise steps which are not required for or present in the methods of the other groups: introducing a cargo moiety to a liposome in the presence of a solvent (Group I), and administering a cargo moiety-cochleate to a subject (Group III). The end results of the methods are different: making a cargo moiety-cochleate (Group I), and treating a subject (Group III).

Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further, the search required for each of Groups I-IV is not required for any other group, and thus restriction for examination purposes as indicated is proper. Due to the different chemical structure of the products, the products of Groups II and IV require separate searches of the patent and non-patent literature. The search for the product of Group II will not necessarily identify the methods of Group I or III. The search for the product of Group IV will not necessarily identify the method of Group I. Moreover, each of the methods require a separate search of the patent and non-patent literature owing to the different method steps not shared with any other group. Therefore, the searches are not coextensive, and the additional searching that is required to search more than one group would impose a serious search burden.

This application contains claims directed to the following patentably distinct species of the claimed invention: methods for forming a cargo moiety-cochleate, a cargo-moiety cochleate and methods of using a cargo moiety-cochleate comprising the following sub-species types:

1) solvent (for example, one combination of solvent comprising one or more solvents of claim 11);

2) cargo moiety (for example, claim 17; one combination of cargo moiety comprising one or more cargo moieties of claim 18; or one of claim 143),

a) if a drug is elected, one member must be elected from claim 19 or claim 20,

b) if a polynucleotide is elected, one member must be elected from claim 21,

c) if a protein is elected, one member must be elected from claim 24,

d) if an antigen is elected, one member must be elected from claim 25,

e) if a nutrient is elected, one member must be elected from claim 26,

f) if a vitamin is elected, one member must be elected from claim 27,

g) if a mineral is elected, one member must be elected from claim 28,

h) if a saccharide or sweetener is elected, one member must be elected from claim 29,

i) if a flavor substance is elected, one member must be elected from claim 31 or claim 32;

3) aggregation inhibitor (for example, one of claim 34, one of claim 118 or one of claim 119); and

4) route of delivery (for example, one of claim 40, 41, 158 or 161).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Upon the election of Group I or II, a single sub-species type must be elected from sub-species types 1-3. Upon the election of Group III, a single sub-species type must be elected from sub-species types 1-4. Currently, claim 1 is generic for Group I; claim 37 is generic for Group II; and claim 38 is generic for Group III.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention: anhydrous cochleates comprising the following sub-species types:

1) a first protonized cargo moiety (for example, one of claim 61 or one of claim 64),

2) a second protonized cargo moiety must be elected (for example, one of claims 71-72), and

3) aggregation inhibitor (for example, one of claim 75).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (one of each sub-species types) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 53 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with the 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

jad

TERRY MCKELVEY
PRIMARY EXAMINER

Continuation of Disposition of Claims: Claims pending in the application are 1-81,102-110,115-124,142-152,154-161,164-166,169-176 and 201-211.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-81,102-110,115-124,142-152,154-161,164-166,169-176 and 201-211.